Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Medical Test Site License Fee Changes

by Gail Neuenschwander

Clinical laboratories in Washington will be faced with a new fee structure when the Medical Test Site (MTS) licenses are renewed in October 2002. This change in the fee structure is due to a major hike in the yearly fee that the state pays to the federal Health Care Financing Administration (HCFA) for exemption from the federal Clinical Laboratory Improvement Amendments (CLIA) program. As previously reported in the September 1999 issue of *Elaborations*, HCFA's basis for the increase in the state's exemption fee is that it would more "fairly and accurately reflect Washington's share in the costs of administering the CLIA program."

Efforts to combat the increase in the exemption fee have not been successful. When notice of the fee increase was received in July of 1999, Washington worked with the congressional delegation, as well as other states that were affected by this fee increase (Oregon, New York, California and Florida), to try and resolve the fee issue. A federal audit of the CLIA program was requested by Senator Wyden from Oregon. The audit report issued in January 2000 stated that the CLIA program had to increase user fees (CLIA laboratories and exempt states) to maintain solvency. Since this brought no relief to the states that had their own programs, Oregon did not renew their CLIA exemption and California and Florida pulled back their exemption applications.

The latest jump in the yearly exemption fee from $97,331 to $374,763 will be phased in starting in April 2001, when Washington's exemption is up for renewal. The license fees collected in October 2000 will keep the MTS program operational until October 2002. At that time a new fee structure that matches the CLIA fee structure will have to be in place to generate additional income to pay the increased CLIA exemption fee. If this is not done, the state MTS program will have to be discontinued. Either option will require legislative action in 2002 to either increase the MTS fees above I-601 limits, or amend or repeal the MTS law to eliminate the need for a state MTS license.

2002 Fees: Regardless of whether the MTS program is retained or turned over to Federal control, **the fees that Washington laboratories will have to pay to hold a laboratory license will be the same.**

What is the impact of losing the State MTS program?

- Oversight of laboratories will fall under federal vs. state jurisdiction;
- HCFA would contract with the state to implement the CLIA program;
- Staffing levels would be based on a national formula which could affect the availability of personnel to answer technical questions, provide educational materials or assist with reimbursement problems;
- Inspection process would be determined by the federal government;
- Federal regulators would decide whether state surveyors or federal surveyors would conduct complaint investigations;
- Any enforcement action taken against a laboratory would be in the hands of the federal government vs. the state;
- Interpretation of regulations would be done by federal regulators, rather than by the state program;
- Application renewals, payment of license fees, license category changes and replacement of lost licenses would be handled by a federal contractor;
- Training classes, technical assistance, newsletters and other educational materials would not be funded;
- Information gathered on the types of testing performed in laboratories in WA would no longer be available.

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Inside This Issue

Pharmacies Jump On The Lab Testing Bandwagon

by Susan Walker

The Department of Health's Laboratory Quality Assurance (LQA) section recently finished relicensing Washington State's 2600 laboratories. Currently, the State has 1025 laboratories with waived licenses; 843 with Provider Performed Microscopic Procedure (PPMP) licenses; 175 accredited licenses; and 557 categorized laboratories that are inspected by LQA. (See Table 1)

One of the major changes the department has seen in the past two years is the increasing number of pharmacies that perform laboratory testing. Of the 1025 waived laboratories, pharmacies hold the number 3 slot (127 out of 1025) for most waived laboratories by site type. Only physician offices and skilled nursing facilities have more waived laboratories. (See Table 2)

With the number of tests classified as waived growing at a rapid pace, more and more people are jumping on the laboratory testing bandwagon. Tests performed by pharmacies include cholesterol, triglyceride, HDL, glucose, glycosylated hemoglobin, urine dipsticks, and protimes. After looking at several major pharmacies' web sites, lab screening, free blood pressure checks, and wellness information are major customer service issues.

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With the proliferation of health information, more people are taking responsibility for monitoring their own health and want to know their laboratory testing results. Pharmacists who work in clinics and hospitals are often the ones responsible for performing protimes and then monitoring the outpatients' medications as part of a coagulation clinic.

Regardless of the testing site, waived testing personnel must follow the manufacturer's instructions for the waived test or kit. As a minimum, the waived laboratory must have an up-to-date package insert for all waived tests and follow any requirements the manufacturer lists.

Table 1

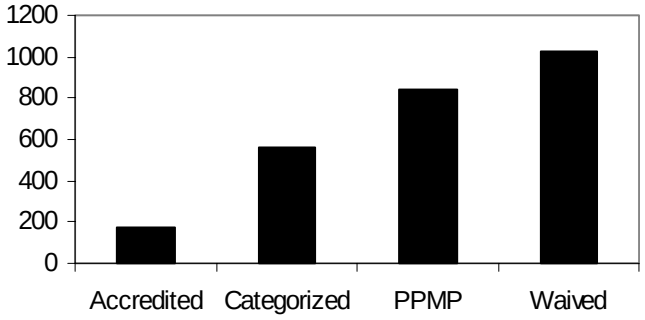
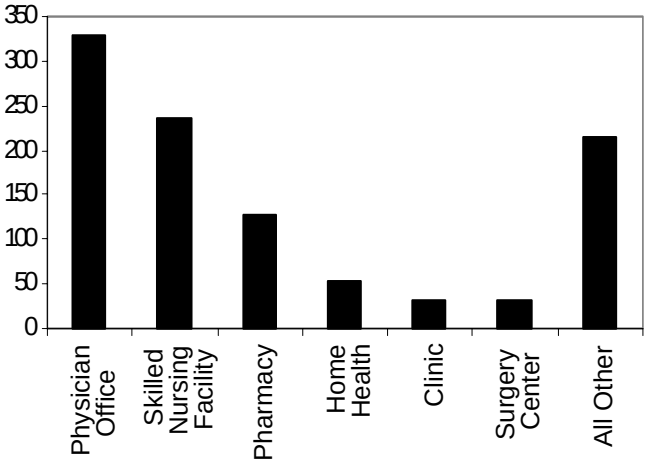


Table 2



		Current MTS Fee	2002 Fees CLIA* or MTS
Certificate of Waiver		$ 108	**$ 150**
PPMP		$ 163	**$ 200**
(Nonaccredited)	**# of Tests**		
Limited Testing	1-750	$ 543	**$ 450**
Low Volume	751-2,000	$ 1,086	**$ 450**
A	2,001-10,000	$ 1,629	**$ 1,364**
B (>3 specialties)	2,001-10,000	$ 1,955	**$ 1,769**
C	10,001-25,000	$ 2,281	**$ 2,454**
D (>3 specialties)	10,001-25,000	$ 2,715	**$ 2,818**
E	25,001-50,000	$ 3,259	**$ 3,382**
F	50,001-75,000	$ 3,802	**$ 4,187**
G	75,001-100,000	$ 4,453	**$ 4,991**
H	100,001-500,000	$ 5,105	**$ 5,835**
I	500,001-1,000,000	$ 5,432	**$ 10,369**
J	>1,000,000	$ 5,974	**$ 12,443**
(Accredited)			
Limited Testing	1-750	$ 325	**$ 165**
Low Volume	751-2,000	$ 325	**$ 165**
A	2,001-10,000	$ 325	**$ 211**
B (>3 specialties)	2,001-10,000	$ 325	**$ 231**
C	10,001-25,000	$ 325	**$ 531**
D (>3 specialties)	10,001-25,000	$ 325	**$ 559**
E	25,001-50,000	$ 325	**$ 787**
F	50,001-75,000	$ 325	**$ 1,254**
G	75,001-100,000	$ 325	**$ 1,722**
H	100,001-500,000	$ 325	**$ 2,227**
I	500,001-1,000,000	$ 325	**$ 6,428**
J	>1,000,000	$ 325	**$ 8,168**

NOTE: Under the current MTS fee schedule, complete blood counts (CBC) are counted as one test.

Under the new fee schedule, **each CBC parameter** (RBC, WBC, hemoglobin, hematocrit, platelets, differential) **will be counted as separate tests** as they are under CLIA. This would increase the total test volume and could place some sites in a higher category.

NOTE: *Under CLIA, laboratories would pay an <u>additional</u> one-time $100 registration fee.

Additional Waived / PPMP Procedures

The Office of Laboratory Quality Assurance has received notice from the Health Care Financing Administration that the following procedures have been added to the list of waived tests under CLIA:

Test:	Effective Date:	CPT Code:
▪ Ballard Medical Products CLOtest	10-5-99	87077QW
▪ Lifesign Status *H. pylori* (whole blood)	10-5-99	86318QW
▪ Abbott Laboratories Medisense Products Precision Xtra Advanced Diabetes Management System [ketone]	2-28-00	82010QW
▪ Polymer Technology Systems Bioscanner Test Strips Cholesterol	4-03-00	82465QW
▪ JANT Pharmacal Corp. *H. pylori* WB Test	4-13-00	86318QW
▪ Polymedco, Inc. Poly stat Mono for Infectious Mononucleosis [whole blood]	4-13-00	86308QW
▪ Polymedco, Inc. Poly stat *H. pylori* [whole blood]	4-13-00	86318QW
▪ Polymedco, Inc. Poly stat A (II) for Group A Strep [direct from throat swab]	4-13-00	87880QW
▪ Phamatech At Home Drug Test Individual Test kits for Amphetamine, Methamphetamines, Cocaine Metabolites, Cannabinoids, Opiates, or Phenycyclidine	4-19-00	80101QW
▪ Phamatech At Home Drug Test Combination Kits	4-19-00	Pending
▪ Teco Diagnostics URITEK TC-101 Urine Strip Reader	5-10-00	81003QW
▪ Remel RIM A.R.C. *H. pylori* Test (WB)	5-12-00	86318QW
▪ Princeton BioMediTech BioStrep A Test	5-17-00	87880QW
▪ LifeSign LLC Stratus Strep A	5-17-00	87880QW
▪ Worldwide Medical Corporation, First Check Home Drug Test Panels	6-29-00	Pending
▪ Polymer Technology Systems, Inc., Bioscanner 2000 [triglyceride}	7-06-00	84478QW
▪ Trinity Uni-Gold *H. pylori* [whole blood]	7-11-00	86318QW
▪ Lifestream Technologies Personal Cholesterol Monitor for cholesterol	7-21-00	82465QW
▪ Roche Diagnostics CoaguChec S Systems Test [Prothrombin Time]	9-1-00	Pending
▪ Abbott Laboratories, Medisense Products Precision Xtra Advanced Diabetes Management System [glucose]	9-11-00	Pending
▪ Metrika, Inc, DRx HbA1c (prescription home use and professional use models) for glycated hemoglobin	9-26-00	Pending
▪ Quidel QuickVue Influenza Test [Influenza A/B]	10-4-00	87899QW
▪ ZymeTX Zstatflu Test (Influenza A/B)	12-4-00	Pending
▪ OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test	12-19-00	Pending
▪ OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test	1-22-01	Pending

Dr. Romesh Gautom: New PHL Lab Director

by Jac Davies

On February 5, 2001, Romesh Gautom, PhD, became the new Director of the Washington State Public Health Laboratories (PHL). Previously, Dr. Gautom had served as Director of the Office of Public Health Microbiology at the PHL and as Molecular Epidemiologist, managing the PHL's Molecular Methods Development laboratory. His PhD is from the Institute for Advance Studies at Meerut University in Meerut, India. He completed a post-doctoral fellowship with Dr. Tom Fritsche in the Department of Laboratory Medicine at the University of Washington Medical Center, and served as a Senior Fellow in Clinical and Public Health Medical Microbiology in the same department.

Dr. Gautom brings considerable technical experience to his new role. At the PHL, he has established a strong track record for developing innovative new methods to investigate diseases of public health interest. Of particular value has been a new rapid DNA fingerprinting procedure based on Pulsed-Field Gel Electrophoresis. This procedure allows specific identification of strains of *E.coli* O157:H7 and a variety of other infectious disease agents within 24 hours, and has formed the basis of the national PulseNet system, operated by the Centers for Disease Control to track national foodborne disease outbreaks.

In accepting the position of PHL Director, Dr. Gautom emphasized his personal goal of "making a significant improvement in people's lives by developing methodologies directed towards lessening the burden of diseases that plague our world." In keeping with this goal, he has already established an aggressive methodology development program at the PHL, with DNA fingerprint libraries currently under development for a large number of infectious disease agents including various serotypes of *Salmonella*, Vancomycin Resistant Enterococci, Methicillin Resistant *Staphylococcus aureus*, *Bordetella pertussis*, *Listeria monocytogenes*, *Legionella* spp., and *Vibrio parahaemolyticus* from clinical and environmental sources.

Dr. Gautom recognizes the role of the private sector clinical and environmental laboratory system in protecting and improving public health. To this end, he intends to pursue collaboration across the laboratory community, and will participate actively on the state's Clinical Laboratory Advisory Council.

Fee Increase, continued from page 1

What is the magnitude of the fee increase? (see Fee Table, page 3) The MTS fees will be set at the same level they would be under a federal CLIA program. The only difference in MTS fees vs. CLIA fees would be that under CLIA laboratories would pay an additional one-time $100 registration fee.

Meetings will be held throughout the state to discuss the fee increase with stakeholders. **LQA staff will be available to answer questions at the WSSCLS/NWSSAMT Spring Meeting in Spokane on April 19 and 20.** A list of additional meeting times will be printed in the April issue of Elaborations and posted on the LQA website: www.doh.wa.gov/hsqa/fsl/LQA_home.htm.

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Calendar of Events

PHL Training Classes:

Basic Course in Parasitology: Reading Trichromes
April 3 & 4 Shoreline

Lab Regulations: Making Compliance Easier
May 9 Shoreline
May 10 Spokane

Clinically Relevant Microbiology
June 8 Shoreline
June 9 Shoreline

WSSCLS/NWSSAMT Spring Meeting
April 19-21 Spokane

Northwest Medical Laboratory Symposium
October 10 - 13 Portland

8th Annual Clinical Laboratory Conference
November 12 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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